SEP 2 2 2004

510(k) Summary of Safety and Effectiveness

Submitter Information:

Invivo Research Inc.
12601 Research Parkway
Orlando, FL 32826
407-275-3220
Contact: Mr. Neil Battiste

Product Name:

Proprietary: Magnitude™ 3150M MRI Monitor
Common: Multparameter Patient Monitor
Classification: Anesthetic Gas Analyzer, enflurane - (73 CBO/21CFR 868.1500 Class II)
Anesthetic Gas Analyzer, halothane - (73 CBO/21CFR 868.1620 Class II)
Oxygen Gas Analyzer - (73 CBO/21CFR 868.1720 Class II)
Thermometer, Electronic, Clinical - (73 CBO/21CFR 880.2910 Class II)

Predicate Devices:

The predicate devices are the temperature option of the Invivo Research Millennia Vital Sign Monitor (reference 510(k) Number K974581), the Luxtron 3100 Biomedical Flouroptic Thermometer. (reference 510(k) Number K923189) and the Schiller Medical Maglife C (reference 510(k) Number K023195). This predicate devices have the same performance specifications as the temperature option of the Magnitude™ 3150M MRI Monitor.

The temperature option of this device utilizes a Fabry-Pérot interferometer to determine accurate temperatures from 21°C to 44°C.

Device Description:

The 3150M Fiber-Optic Temperature option enables the measurement of a patient's surface temperature both safely and accurately during all MRI procedures. This option utilizes a fiber-optic cable for interface between the temperature sensor at the patient application site and the measuring device. With this scheme, light channeled through a fiber-optic cable is the medium of temperature measurement rather than electrical conductor based components. The fiber-optic cable is impervious to the RF energy present during MRI procedures, thus eliminating the possibility of heating.

The Fiber-Optic Temperature option contains four items: 1) Re-usable fiber optic surface temperature sensor. 2) Disposable surface temperature sensor applicator for use on patients ranging from Neonatal (5 kilograms) to Adult. 3) Fiber optic connector on the outside of the 3150M. 4) Signal conditioner inside 3150M patient monitor.

Intended Uses:

The Invivo Research Inc. Magnitude™ 3150M MRI Monitor is a device comprised of two separate monitors: the 3150M Monitor, which operates as the base monitor, and the 3155 Monitor, which operates as a Remote Display monitor. The 3150 and 3155 Monitors communicate through a bi-directional radio-link which operates within the MRI area. Both monitors display the patient information, and must be used together for the system to operate. A warning message is displayed if the radio-link is broken.

The Invivo Research Inc. Magnitude™ 3150M MRI Monitor is intended for general hospital or clinical use within a magnetic resonance imaging (MRI) area by medical professionals whenever it is required to monitor concentrations of anesthetic gases. The agents monitored include halothane, enflurane, isoflurane, sevoflurane and desflurane. Additionally, this monitor also monitors end-tidal carbon dioxide, nitrous oxide, oxygen gas concentrations, ECG, non-invasive blood pressure, invasive blood pressure and temperature. This device is available for sale only upon the order of a physician or other related licensed medical professional.

Summary of Performance Testing:

The Invivo Research Inc. Magnitude™ 3150M MRI Monitor conforms with national and available international product safety standards for electrical, electromagnetic compatibility, and anesthetic agent monitoring. This device was verified to function per the following specifications:

PARAMETER	SPECIFICATION
Temperature Range	20 to 44°C
Accuracy	± 0.3°C
Resolution	± 0.1°C
Time to Steady State	< 150 seconds
Output format	Selectable °C, °F
Storage Temperature	-20°C to 50°C
Operating Temperature	16°C to 40°C
Relative Humidity	15% to 95% RH non-condensing
Battery Condition	± 0.3°C
Cleaning test	Minimum of 5 times with detergent

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 2 2004

Invivo Research, Inc.
c/o Mr Neil Battiste
Director, Regulatory Affairs
12601 Research Parkway
Orlando, FL 32826

Re: K040915
Trade Name: Magnitude™ 3150M MRI Monitor
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including cardiotachometer and rate alarm)
Regulatory Class: II (two)
Product Code: MWI
Dated: August 27, 2004
Received: September 02, 2004

Dear Mr. Battiste:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K040915

Indications for Use

510(k) Number (if known): K040915

Device Name: Magnitude™ 3150M MRI Monitor

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K040915